IMPLEMENTING THE 2016 TSCA AMENDMENTS— PROGRESS & PROGNOSIS

Panel 1: Analysis of regulatory proposals

- regulatory proposals issued pursuant to the amended Section 6(a) of TSCA,
- proposed prioritization and risk evaluation rules,
- Inventory rule identifying "active" and "inactive" substances,
- public meeting on the scope of the first 10 risk evaluations EPA will undertake.

Prioritization rule:

1. EPA officials have said that substances for which only limited use and exposure or hazard information is available are **unlikely** to be candidates for pre-prioritization. Does this seem consistent with Congressional intent? Other comments or concerns?

[Prioritization/Risk Evaluation rules:]

2. Does this [limitation on candidates for pre-prioritization] reject the Agency's Statutory testing authority?

> *§4(a)(2)(B) "the Administrator may require the development of new information for the purposes of prioritizing a chemical substance under section 6(b) only if the Administrator determines that such information is necessary to establish the priority of the substance, subject to the limitation that*
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> > *(i)not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, order, or consent agreement under this subparagraph, the administrator shall designate the substance as a high-priority substance or a low-priority substance;*

3. To quote from the proposed rule (p. 7568, ¶D):

> Generally speaking, EPA does not consider information that has not yet been generated, as reasonably available, because it will typically not be feasible for EPA to require significant chemical testing and receive and assess those test results during the three to three and a half year window allotted for risk evaluation.

I'd like your thoughts on this position. Again the statute explicitly provides testing authority by order if the Administrator determines that the information is necessary to perform a risk evaluation. Why would Congress write such language into the statute if it did not intend the Agency to use it?

Prioritization/Inventory Reset rules:

4. It seems a bit paradoxical that the Agency isn't using the Inventory Reset data collection to gather use and exposure information and maybe even hazard information that could be used for prioritization. Your thoughts?

Inventory Reset rule:

5. In identifying the substances subject to Inventory Reset, did the Agency miss an opportunity to identify substances manufactured in the course of manufacturing articles? Such substances are presently exempt from PMN requirements. Yet EPA is now tasked with determining whether there is a risk presented by exposure to substances contained in articles. How can they Agency begin to identify the risks presented by these substances without first identifying the universe of the chemicals?

Risk Evaluation rule:

6. In the proposed rule, EPA notes that it is purposely not proposed a definition of unreasonable risk because of the case-by-case nature of the many factors weighed in assessing risk. EPA also solicited comments on whether the Agency should define unreasonable risk in the final rule. Should the Agency define unreasonable risk in the final rule? What factors should EPA consider in making such a determination?

7. The description of risk-characterization (p. 7571, I.4) in the proposed rule is fairly limited. The Agency opens with the statement,

   > A risk characterization conveys the risk assessor's judgment as to the nature and presence or absence or risks, along with information about how the risk was assessed, where assumptions and uncertainties still exist, and where policy choices will need to be made.

   What would you ask the Agency to also consider? What role should policy choices play in the risk evaluations?

6(a) Methylene Chloride/NMP:

8. I'd like to get your impressions of the proposed methylene chloride NMP section 6 rule. For example, do you think the proposed use restrictions are adequate or reasonable, such as EPA's second co-proposal for NMP that would require product reformulation to limit the concentration of NMP in paint and coating removal products, testing of product formulations to identify specialized gloves that would provide protection for users, relabeling of products intended for consumer use to provide additional information to consumers, an occupational dermal and respiratory protection program for commercial use, and so on.

9. Although EPA proposes to determine that the identified risks to workers exposed to methylene chloride in commercial furniture refinishing are unreasonable, EPA is not proposing regulate these risks at this time. EPA intends to issue a separate proposal addressing the use of methylene chloride in paint and coating removal in commercial furniture refinishing. Is this a reasonable approach to the risks posed to worker health? Should employers or manufacturers want a more rigorous approach to protect them from tort liability?